Information Manual

CE 0123

Fingertip Pulse Oximeter

FDA 1.0C3

MD300C3, MD300C31, MD300C32, D300C33

1.Measurement principle

The Oximeter is calibrated to display functional oxygen saturation. Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(R Hb) and Oxyhemoglobin (O2 Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs through process in electronic circuits and microprocessor.

2.Precautions for use

- *Operation of MD300C3 may be affected by the use of an electrosurgical unit (ESU).*
- *The MD300C3 must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before replying on the SpO2 measurement.*
- Do not use the MD300C3 in an MRI or CT environment
- Do not use the MD300C3 in situations where alarms are required. The device has no alarms.
- Explosion hazard: Do not use the MD300C3 in an explosive atmosphere.
- The MD300C3 is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the pulse Oximeter sensor application site *frequently* to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
- Do not stretch the adhesive tape while applying the pulse Oximeter sensor. This may cause inaccurate readings or skin blisters.
- Before use, carefully read the manual.
- The MD300C3 has no SpO2 alarms, it is *not for continuous monitoring,* as indicated by the symbol.
- Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

3.Inaccurate measurements

- *Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid which may cause inaccurate readings. The device is not intended for sterilization.*
- Significant levels of dysfunctional hemoglobins (such as carbonxy- hemoglobin or methemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- Excessive patient movement
- High-frequency electrosurgical interference and defibrillators
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- The patient is in cardiac arrest or is in shock
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

4.Technical Specifications

4.1 Display type: LCD display
SPO2 display range: 0-100%
PR display range: 30-235 BPM
PR display mode: bargraph
Data update time: < 15 s

4.2 LED Wavelengths
Red: 660nm
Infrared: 940nm

4.3 Battery life
Two AAA 1.5V alkaline batteries could be continuously operated as long as 30 hours.

4.4 Resolution: ±1% for SPO2 and ±1BPM for Pulse rate

4.5 Measurement Accuracy:
SPO2: 80%--100%±2%; 70%--79 ±3%; ≤70% no definition.
PR: 30—235 BPM, ± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-235 bpm

4.6 It is equipped with a function switch, through which the Oximeter can be powered off in case no finger is the Oximeter longer than 8 seconds.

4.7 Outline dimension:
Length: 60mm
Width: 34mm
Height: 30mm
Weight: 50g (including two AAA batteries)

4.8 Environment requirements:
Operation Temperature: 5-40℃
Storage Temperature: -20-70℃
Humidity : 15%-80% in operation
<93% in storage
Declaration: EMC of this product comply with IEC60601-1-2 standard.

5.Product Properties

5.1 Operation of the product is simple and convenient
5.2 The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying
5.3 Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
5.4 Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the Oximeter might be influenced.
5.5 The product will automatically be powered off when no signal is in the product for longer than 8 seconds.
5.6 PR tone modulation
5.7 Brightness adjustment

6. Product Intended Use

Intended Use:

Fingertip Pulse Oximeter MD300C3 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.
The MD300C3 requires no routine calibration or maintenance other than replacement of batteries.

7. Operation Instructions

7.1 Installing two AAA batteries into battery cassette before covering its cover.
7.2 Open the clamp as illustrated in the picture below
7.3 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp
7.4 Press the switch button once on front panel.
7.5 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status
7.6 Read correspondent datum from display screen.
7.7 Six display modes

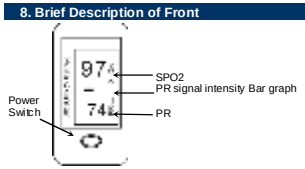
After turn on the oximeter, each time you press the power switch, the oximeter will switch to another display mode, there are 6 display modes shown as follows

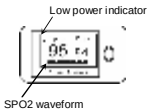
Display Mode	Description
	Display mode when opening the device, horizontal and normal facing
	After 1 click, the display is horizontal but handstand facing
	After 1 click again, the display is vertical and handstand facing
	After another click, the display is vertical and normal facing
	After another click again, the display is horizontal and normal facing with wave-shape filled form display
	After 1 click once more, the display is horizontal and normal facing with wave-shape wire form display

When you press the power switch for a long time (more than one second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

When your finger is plugged into the Oximeter, your nail surface must be upward.

8. Brief Description of Front





Patient pulse quality signals are indicated as such by bar graph. The bar is graded as 10 levels, if the strength is two to three level, the pulse signal is inadequate.

9. Product Accessories

9.1 One hang lace
9.2 Two batteries
9.3 One instruction manual

10. Battery Installations

10.1 Put the two AAA batteries into battery cassette in correct polarities.
10.2 Push the battery cover horizontally along the arrow shown as below:

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Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.
Please put or remove batteries in right order, or is likely to damage the device bracket.
Please remove the battery if the Oximeter will not be used for long time

11.Hang Lace Installations

11.1 Thread thinner end of the hang lace through the hanging hole
11.2 thread thicker and of the lace through the threaded end before pulling it tightly.

12.Maintenance and Storage

12.1 Replace the batteries timely when low voltage lamp is lighted
12.2 Clean surface of the fingertip Oximeter before it is used in diagnosis for patients
12.3 Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time
12.4 It is best to preserve the product in a place where ambient temperatures –10-40℃ (14-104℉) and humidity is 10%-80%
It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
Please follow the law of the local government to deal with used battery

Cleaning the MD300C3

Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter with a soft cloth dampened with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test.
Do not pour or spray and liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reusing.

13.Calibrating the MD300C3

- The functional tester cannot be used to assess the accuracy of the oximeter.
- Index 2 that made by Bioteck company is a function tester. Set Tech to 1, R curve to 2, then user can use this particular calibration curve to measure the oximeter.
- The test methods used to establish the SpO2 accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

14. Possible Problems and res

Problems	Possible reason	Solution
SpO2% or pulse rate can not be shown normally	1. Finger is not plugged correctly 2. Patient's SpO2value is too low to be measured	1.Retry by plugging the finger 2. There is excessive illumination 3. Measure more times, If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis
SpO2% or pulse rate is shown unstably	1. Finger might not be plugged deep enough 2. Excessive patient movement	1. Retry by plugging the finger 2. Be calmness.
The Monitor can not be powered on	1.No battery or low power of battery 2.Battery might be installed incorrectly 3. The Monitor might be damaged	1. Please replace battery 2. Please reinstall the battery 3. Please contact with local customer service centre
Indication is suddenly off	1. The oximeter is automatically powered off when no signal is detected longer than 8 seconds 2. The batteries power is too low to work	1. Normal 2. Replace the battery
"Error3" or "Error4" Displayed on screen	1. Err 3 means the red emission LED is damaged. 2. Err 4 means the infra-red emission LED is damaged.	1. Check the red emission LED 2. Check the infra-red emission LED
Error 6	Err 6 means the crystal is failure	Change the crystal
"Error7" displayed on screen	Err 7 means all the emission LED or reception dioxide is damaged.	Check the emission LED and reception dioxide.

15. Declaration

Guidance and Manufacture's declaration – electromagnetic emissions-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacture's declaration - electromagnetic emission		
Guidance and Manufacture's declaration – electromagnetic environment specified below. The customer of the user of the *Pulse Oximeter (MD300C3)* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic Environment – guidance**
RF emissions CISPR 11	Group 1	The pulse Oximeter (MD300C3) uses RF energy only for very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The pulse Oximeter (MD300C3) is suitable for use in all establishment, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-2	Not Applicable	

Guidance and Manufacture's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS

Guidance and Manufacture's declaration - electromagnetic immunity			
Guidance and Manufacture's declaration – electromagnetic environment specified below. The customer of the user of the *Pulse Oximeter (MD300C3)* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- kV contact +/- 8kV air	+/- kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacture's declaration – electromagnetic immunity-
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacture's declaration - electromagnetic immunity			
Guidance and Manufacture's declaration – electromagnetic environment specified below. The customer of the user of the Pulse Oximeter (MD300C3) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment – guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter (MD300C3), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 80 MHz to 800 MHz 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people.			
A Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter (MD300C3) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (MD300C3). B Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS -
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and *Pulse Oximeter (MD300C3)*		
The *Pulse Oximeter (MD300C3)* is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Pulse Oximeter (MD300C3)* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Pulse Oximeter (MD300C3)* as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**	
	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.1167	0.2334
0.1	0.3689	0.7378
1	1.1667	2.3334
10	3.6893	7.3786
100	11.6667	23.3334
For transmitters rated at a maximum output power not listed above, the recommended sepratation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

16. Symbol Definitions

Symbol	Definition
	The equipment type is BF
	Refer to user manual before application
	Hemoglobin saturation
	Heart rate (BPM)
	Low power indication
	Serial No
	No for continuous monitoring

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